

## **REMARKS**

Claims 1-12, 19-23, 25-28, 30, 36-48, 58-65, and 67-79 are pending. Claims 1, 5-12, 30, 36-39, and 67-72 remain under consideration in the case. Of the pending claims, claims 2-4, 19-23, 25-28, 40-48, 58-65, and 73-79 have been withdrawn by the Examiner. [Paper No. 040505 at 1-3].

Claims 13-18, 24, 29, 31-35, 49-57, 66, and 80 have been cancelled, without prejudice.

Claim 1 has been amended to correct certain minor informalities, which do not alter the scope of the claim. Support for this amendment is found in the specification at, for example, page 5, line 23 - page 6, line 7. *See In re Gardner*, 177 USPQ 396, 397 (CCPA 1973) and MPEP §§ 608.01(o) and (l).

Claim 30 has been amended to correct a minor informality and to recite that the bone fastener is “made of a” bioresorbable “PLA/PLG copolymer.” Support for this amendment is found in the specification at, for example, page 9, lines 4-5; page 10, lines 23-24; page 10, line 30 - page 11, line 11; and original claims 46-48. *Id.*

Claim 81 has been added. Support for claim 81 is found in the specification at, for example, page 10, lines 23-24; page 19, lines 4-15; and original claim 1. *Id.*

It is submitted that no new matter has been introduced by the foregoing amendments and added claim. Approval and entry of the amendments and added claim is respectfully solicited.

### **Rejections Under 35 USC §102(b)**

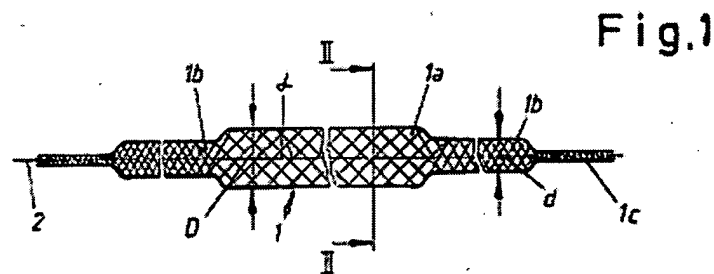
#### **A. Mansat, US Patent No. 4,728,329**

Claims 1, 5-12, 30, 36-39, and 67-72 were rejected under 35 USC §102(b) as anticipated by Mansat, US Patent No. 4,728,329 (“Mansat”). [Paper No. 040505 at 3].

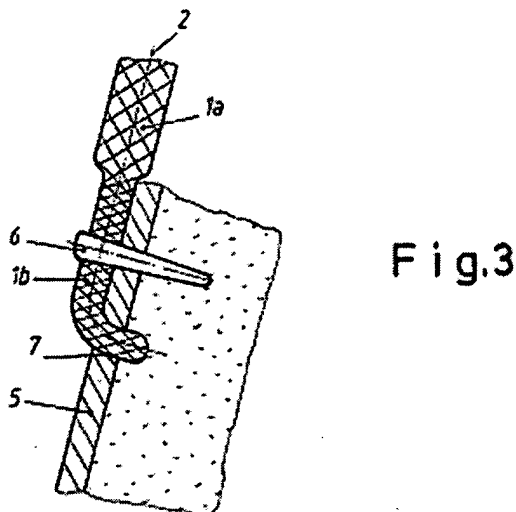
For the reasons set forth below, this rejection is respectfully traversed.

Mansat discloses “a prosthetic band which is capable of use as a prosthetic tendon.” [Column 1, lines 5-6]. Mansat exemplifies the prosthetic band as a “transverse or cruciate ligament of a knee joint.” [*Id.*, Column 2, lines 23-24].

Mansat discloses that the structure of the prosthetic band “is comprised of a plurality of concentric sleeve-like elements which define a shaft having a central flexible zone and a pair of rigid end zones.” [*Id.*, Column 1, lines 51-53]. With reference to Figure 1, Mansat discloses that “the band 1 has a central flexible zone 1a of a diameter D which merges at each end into a rigid end zone 1b of a diameter d. To this end, each end zone 1b has a relatively reduced flexibility with respect to the central zone 1a. ... The band 1 also has thin leader parts 1c extending from each rigid zone 1b.” [Column 3, lines 3-7 and 17-18]. For the Examiner’s convenience, Figure 1 is reproduced below:



Mansat also discloses that the band is secured to a bone by “hammering” a “brace” or an “agraffe” through an end zone into the bone. [See *e.g.*, Column 2, lines 32-56; Column 3, line 62 - Column 4, line 2; and Fig. 3]. For the Examiner’s convenience, Fig. 3 is reproduced below:



In making the rejection, the Examiner contended only that:

Mansat discloses a connection system comprising a ligament and first and second bone fasteners. The ligament is made of a braided fabric and

includes a central portion, first and second end portions and first and second conformable portions disposed between the end portions and the central portion. The fasteners may be shoulderless (see figure 3).

[Paper No. 040505 at 4].

As is well settled, anticipation requires “identity of invention.” *Glaverbel Societe Anonyme v. Northlake Mktg. & Supply*, 33 USPQ2d 1496, 1498 (Fed. Cir. 1995). Each and every element recited in a claim must be found in a single prior art reference and arranged as in the claim. *In re Marshall*, 198 USPQ 344, 346 (CCPA 1978); *Lindemann Maschinenfabrik GMBH v. American Hoist and Derrick Co.*, 221 USPQ 481, 485 (Fed. Cir. 1984).

Initially, we note that the rejection fails to identify where Mansat discloses that the respective end portions of the ligament are shaped to “cooperatively connect” to the bone fasteners as recited in claims 1 and 67. Thus, the rejection fails to meet the “identity of invention” requirement. For this reason alone, the rejection should be withdrawn.

It is also incumbent upon the Examiner to “*identify wherein each and every facet of the claimed invention is disclosed in the applied reference.*” *Ex parte Levy*, 17 USPQ2d 1461, 1462 (BPAI 1990). The Examiner is required to point to the disclosure in the reference “*by page and line*” upon which the claim allegedly reads. *Chiong v. Roland*, 17 USPQ2d 1541, 1543 (BPAI 1990). Moreover, when relying on a figure, the Examiner is required to explain wherein the figure each element of the rejected claim may be found and how the figure anticipates the claim. *See, e.g., Ex part Nagao*, 1995 WL 1759119, \*3-4 (BPAI 1995) (unpublished) (“We note that the examiner did not make clear what elements in the Gold Figure 7 correspond to the claimed ‘multi-dimensional image’, ‘image elements’ and ‘multidimensional regions’ as recited in Appellant’s claims.”); and *Ex Parte Jezequel*, 1997 WL 1948956, \*2 (BPAI 1997) (unpublished) (“Indeed, the particular portions of the figures ... have not been adequately identified by the examiner.”).

The rejection fails to identify wherein Mansat each and every element of claims 1 and 67 are shown. All that the rejection does is list a series of elements recited in the rejected claims, without any attempt to identify wherein Mansat the identified elements

are allegedly described. Moreover, the only instance where the rejection is specific with respect to a claim element - “shoulderless” fasteners - all we are told is to “see figure 3.” That alone is not enough.

Figure 3 depicts a cross-section of one end of the prosthetic band secured to a bone by a brace or an agraffe, which passes through an end zone and into the bone. It is respectfully submitted that Figure 3 does not disclose or suggest a “shoulderless bone fastener” as recited in claims 1 and 67. Thus, the rejection does not identify wherein Mansat there is found a description of any element of claims 1 and 67, let alone, each and every element of claims 1 and 67. Thus, the rejection is insufficient as a matter of fact and law, and should be withdrawn for this additional reason.

Claim 30, as amended, recites, *inter alia*, that the “bone fastener is made of a bioresorbable PLA/PLG copolymer and is shoulderless.” The rejection has not - and cannot - identify where Mansat discloses or suggests that the device used to secure the prosthetic band to the bone is “made of a bioresorbable PLA/PLG copolymer and is shoulderless” as recited by claim 30. Nor does the rejection identify with specificity wherein Mansat any of the other recited elements of claim 30 are disclosed or suggested. For at least these reasons, it is respectfully submitted that the rejection of claim 30 is deficient and should be withdrawn.

Claim 36 recites that the respective bone fastener be “pre-connected” to the respective end portions of the ligament. The rejection has not - and cannot - identify where Mansat discloses or suggests such an element. Nor does the rejection identify with specificity wherein Mansat any of the other recited elements of claim 36 are disclosed. Accordingly, for at least these reasons, the rejection of claim 36 should be withdrawn.

For the reasons set forth above with respect to claims 1, 30, 36, and 67, it is respectfully submitted that the claims that depend therefrom, *i.e.*, claims 5-12, 37-39, and 68-72 are also not anticipated by Mansat. We further note that the rejection fails to address - let alone identify wherein Mansat there is found - a single element recited by any of the dependent claims. For this reason also, the rejection of claims 5-12, 37-39, and 68-72 should be withdrawn.

In sum, for the reasons set forth above, it is respectfully requested that the Examiner withdraw the rejection of claims 1, 5-12, 30, 36-39, and 67-72.

**B. Yuan and Lin, US Patent No. 5,681,310**

Claims 1, 5, 7-9, 11, 12, 30, 36-39, 67-69, 71, and 72 were rejected under 35 USC §102(b) as anticipated by Yuan and Lin, US Patent No. 5,681,310 (“Yuan”). [Paper No. 040505 at 4].

For the reasons set forth below, this rejection is respectfully traversed.

Yuan discloses “[a] vertebral auxiliary fixation device [that] comprises a holding mat and a plurality of fastening elements.” [Abstract]. Yuan discloses that the device is “capable of holding an implanted graft or filling.” [Column 1, lines 9-11].

Yuan discloses that both the holding mat and the fastening elements “may be made of a biocompatible material.” [Column 2, lines 22-27]. Yuan exemplifies “Dacron” as a “biocompatible material.” [Column 1, lines 61-63].

Yuan discloses that the fastening elements may be “screws,” “hooks,” or “staple shaped.” [Column 2, lines 5-10; Column 3, line 22-23; and Figs. 2-6]. Yuan also discloses that the holding mat is secured to a vertebrae by inserting a plurality of the fastening elements through the mat and into the vertebrae. [See, e.g., Column 2, lines 5-14; Figs. 1-6; and claim 1]. Figures 2-6, reproduced below, depict the fastening element embodiments disclosed in Yuan.

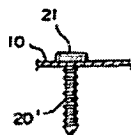


FIG. 2

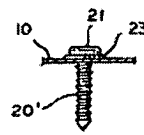


FIG. 3

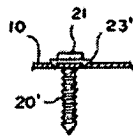


FIG. 4

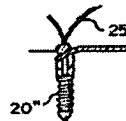


FIG. 5



FIG. 6

In making the rejection, the Examiner contended only that:

Yuan et al. disclose an intervertebral connection system comprising a ligament and first and second bone fasteners. The ligament is made of a fabric and includes a central portion, first and second end portions and first and second conformable portions disposed between the end portions and the central portion. The fasteners may be shoulderless (see figure 5).

[Paper No. 040505 at 4].

As noted above, anticipation requires “identity of invention.” *Glaverbel Societe Anonyme*, 33 USPQ2d at 1498. Each and every element recited in a claim must be found in a single prior art reference and arranged as in the claim. *Marshall*, 198 USPQ at 346; *Lindemann Maschinenfabrik GMBH*, 221 USPQ at 485.

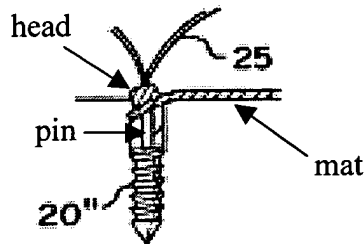
Initially, we note that the rejections based on Yuan and Mansat are substantially identical. Thus, the Yuan rejection, like the Mansat rejection, fails to identify where Yuan discloses that the respective end portions of the ligament are shaped to “cooperatively connect” to the bone fasteners as recited in claims 1 and 67. Thus, the Yuan rejection fails to meet the “identity of invention” requirement. For this reason alone, the rejection should be withdrawn.

Also as noted above, it is incumbent upon the Examiner to “*identify wherein each and every facet* of the claimed invention is disclosed in the applied reference.” *Levy*, 17 USPQ2d at 1462. The Examiner is required to point to the disclosure in the reference “*by page and line*” upon which the claim allegedly reads. *Chiong*, 17 USPQ2d at 1543. Moreover, when relying on a figure, the Examiner is required to explain wherein the figure each element of the rejected claim may be found and how the figure anticipates the claim. *See e.g., Nagao*, 1995 WL 1759119 at \*3-4; and *Jezequel*, 1997 WL 1948956 at \*2.

The rejection fails to identify wherein Yuan each and every element of claims 1 and 67 are shown. All that the rejection does is list a series of elements recited in the rejected claims, without any attempt to identify wherein Yuan the identified elements are allegedly described. Moreover, the only instance where the rejection is specific with respect to a claim element - “shoulderless” fasteners - all we are told is to “see figure 5.” That alone is not enough.

Figure 5 depicts a sectional view of a fastening element main body 20”, which is provided with a fastening cord 25. In the Figure, however, the head is secured to the

fastening element main body apparently through a pin. To secure the mat to a bone, we presume that the hole in the mat through which the pin is driven is smaller than the diameter of the head. Thus the mat is sandwiched between the head and the body of the fastening element as shown below.



**FIG. 5**

There is no disclosure or suggestion in the Yuan specification, including the claims, that the fastening element depicted in Figure 5 - or any figure - is "shoulderless" as recited in claims 1 and 67. Thus, the rejection is insufficient as a matter of fact and should be withdrawn for this additional reason.

Claim 30, as amended, recites, *inter alia*, that the "bone fastener is made of a bioresorbable PLA/PLG copolymer and is shoulderless." The rejection has not - and cannot - identify where Yuan discloses or suggests that the device used to secure the prosthetic band to the bone is "made of a bioresorbable PLA/PLG copolymer and is shoulderless" as recited by claim 30. Nor does the rejection identify with specificity wherein Yuan any of the other recited elements of claim 30 are disclosed or suggested. For at least these reasons, it is respectfully submitted that the rejection of claim 30 is deficient and should be withdrawn.

Claim 36 recites that the respective bone fasteners be "pre-connected" to the respective end portions of the ligament. The rejection has not - and cannot - identify where Yuan discloses or suggests such an element. Nor does the rejection identify with specificity wherein Yuan any of the other recited elements of claim 36 are disclosed. Accordingly, for at least these reasons, the rejection of claim 36 should be withdrawn.

For the reasons set forth above with respect to claims 1, 30, 36, and 67, it is respectfully submitted that the claims that depend therefrom, *i.e.*, claims 5, 7-9, 11, 12,

37-39, 68, 69, 71, and 72 are also not anticipated by Yuan. We further note that the rejection fails to address - let alone identify wherein Yuan there is found - a single element recited by any of the dependent claims. For this reason also, the rejection of claims 5, 7-9, 11, 12, 37-39, 68, 69, 71, and 72 should be withdrawn.

In sum, for the reasons set forth above, it is respectfully requested that the Examiner withdraw the rejection of claims 1, 5, 7-9, 11, 12, 30, 36-39, 67-69, 71, and 72.

#### **Rejection Under §102(e)**

Claims 1, 5-12, 30, 36-39, and 67-72 were rejected under 35 USC §102(e) as anticipated by Trieu *et al.*, US Patent Publication No. 2002/0120270. [Paper No. 040505 at 3]. For the reasons set forth below, withdrawal of this rejection, respectfully, is requested.

Initially, we thank the Examiner for the courtesies extended during a teleconference with the undersigned on about October 6, 2005. During this teleconference, the Examiner agreed to withdraw the rejection based on the Declaration of Hassan Serhan Under 37 CFR §1.131, which was previously filed on September 2, 2003 and considered by the Examiner. During the teleconference, the Examiner agreed that this Declaration fully complies with the requirements of Rule 131 and, therefore, is sufficient to overcome the present rejection. Thus, for the reasons of record, it is respectfully requested that the Examiner withdraw the present rejection of claims 1, 5-12, 30, 36-39, and 67-72 under §102(e).



### CONCLUSION

For the reasons set forth above, entry of the amendments and added claim and withdrawal of all rejections are respectfully requested.

Should there be any remaining or further questions, the Examiner is requested to please contact the undersigned directly.

Respectfully submitted,

Thomas M. DiMauro 10-17-05

Thomas M. DiMauro  
Attorney for Applicants  
Reg. No. 35,490  
DePuy AcroMed  
1 Johnson & Johnson Plaza  
New Brunswick, NJ 08933  
(508) 880-8401